K083073

MAR 1 3 2009

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Establishment Registration #:	1530901
Address:	1800 Triplett Blvd. Akron, Ohio 44306
Telephone Number:	330-475-8600
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	10/15/08

B. Device Information

Trade Name:	Atoll™ Cervico-Thoracic System
Common Name:	Posterior Cervical Instrumentation
Classification:	**Class II** System with the corresponding product codes: **KWP** 888.3050 - Spinal Interlaminal Fixation Orthosis **MNI** 888.3070(b) (1) – Pedicle Screw Spinal System
Predicate Devices:	Theken – Atoll Cervico-Thoracic System (K070638, K080790)
Comparable Device:	DePuy Spine (USA) – Mountaineer OCT Spinal System (K080828)
Material Composition:	Implant Grade Titanium Alloy (Ti-6Al-4V) per ASTM F136 and ISO 5832-3
Subject Device Description:	The Atoll Cervico-Thoracic System is intended for use as an aid in spine fusion. It consists of screws, hooks, rods, and connectors. These components are available in a variety of sizes to allow for a variety of configurations to better fit each individual patient pathology. The Atoll Cervico-Thoracic System components are manufactured from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F136 and ISO 5832-3. To achieve the best results, unless otherwise specifically described in another Theken Spine document, do not use Atoll Cervico-Thoracic System components in conjunction with components for any other system or manufacturer. The purpose of this submission is the addition of a head to head cross connector.

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Intended Use:

The Atoll Cervico-Thoracic System is indicated to promote fusion of the cervico-thoracic regions of the spine (C1 – T3). The intended indications are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Tumors
- Pseudoarthrosis
- Revision of previous cervical and upper thoracic spine surgery

The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The screws are not intended for use in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Atoll Cervico-Thoracic System can also be linked to the Theken Coral Spinal System with the use of transitional rods and rod connectors

C. Substantial Equivalence

The characteristics of the Atoll Cervico-Thoracic System are similar to the following predicate devices:

1. Atoll Cervico-Thoracic System (K070638, K080790) manufactured by Theken Spine.
2. Mountaineer OCT Spinal System (K042508) manufactured by DePuy Spine.

Equivalence for the Atoll Cervico-Thoracic System is based on similarities of intended use, design, and physical characteristics when compared to the predicate devices. Therefore, Theken Spine believes that there is sufficient evidence to conclude that the Atoll Cervico-Thoracic System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Theken Spine, LLC
% Mr. Dale Davison
1800 Triplett Boulevard
Akron, Ohio 44306

MAR 13 2009

Re: K083073
Trade/Device Name: Atoll™ Cervico-Thoracic System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, KWP
Dated: February 20, 2009
Received: February 23, 2009

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

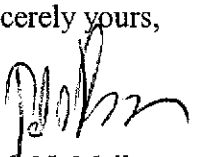
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Atoll™ Cervico-Thoracic System

Indications For Use:

The Atoll Cervico-Thoracic System is indicated to promote fusion of the cervico-thoracic regions of the spine (C1 – T3). The intended indications are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
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Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K084073